



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,690	08/05/2002	Neil J. Rowley	PA-9948	3740

22840 7590 06/29/2004

AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,690	Applicant(s) ROWLEY ET AL.	
	Examiner Michael G. Hartley	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/21/02</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1616

Response to Amendment

The preliminary amendment filed 08 May 2002 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder (US 5,132,309) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

Felder discloses a contrast agent for MRI or X-ray imaging comprising a solution of a metal complex, i.e., a macrocyclic ligand and a metal in a vial (non-radioactive, e.g., Gd), see abstract, columns 2-3 see example 17.

Felder discloses that the non-radioactive metal complex contrast agent compositions are contained in vials, but fails to disclose that the vials are silica coated on the inside.

However it is known in the art that vials that are silica coated on the inside are useful for pharmaceuticals, as shown by Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica, i.e., pure SiO₂, (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the compositions disclosed by Felder (i.e., non-radioactive metal complex diagnostic agent) by using vials having a silica coated

Art Unit: 1616

inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents, as taught DE '958 and Wather, as stated above. One of ordinary skill in the art would have been motivated to use such improved silica coated vials for the pharmaceutical compositions disclosed by Felder to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Wather (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

Claims 1, 5, 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (US 5,545,396) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

Albert discloses a diagnostic composition comprising a hyperpolarized material, such as, Xe-129 or He-3 gas in glass vials, see abstract and examples.

Albert fails to disclose that the vials are silica coated on the inside.

However it is known in the art that vials that are silica coated on the inside are useful for pharmaceuticals, as shown by Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the hyperpolarized diagnostic compositions disclosed by Albert by using vials having a silica coated inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents, as taught by DE '958 and Walther, as stated above. One of

Art Unit: 1616

ordinary skill in the art would have been motivated to use such improved silica coated vials for the pharmaceutical compositions disclosed by Albert to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Walther (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

Claims 1, 5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ardenkjaer-Larsen (US 6,466,814) in view of either one of Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

Ardenkjaer-Larsen discloses a diagnostic composition comprising a hyperpolarized material, such as, hyperpolarized C-13, see column 6, lines 35+.

Ardenkjaer-Larsen fails to disclose that the vials are silica coated on the inside.

However it is known in the art that vials that are silica coated on the inside are useful for pharmaceuticals, as shown by Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the hyperpolarized diagnostic compositions disclosed by Ardenkjaer-Larsen by using vials having a silica coated inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents, as taught by DE '958 and Walther, as stated above. One of ordinary skill in the art would have been motivated to use such improved silica coated

Art Unit: 1616

vials for the pharmaceutical compositions disclosed by Ardenkjaer-Larsen to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by Walther (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

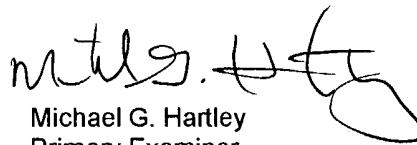
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael G. Hartley
Primary Examiner
Art Unit 1616

6/24/25004